IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUCAMPO AG, SUCAMPO PHARMACEUTICALS, INC., R-TECH UENO, LTD., TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS USA, INC. and TAKEDA PHARMACEUTICALS AMERICA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ANCHEN PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Sucampo AG, Sucampo Pharmaceuticals, Inc., R-Tech Ueno, Ltd., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc. and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Anchen Pharmaceuticals, Inc., Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sucampo AG is a Swiss corporation with its primary place of business at Baarerstrasse 22, CH-6300, Zug, Switzerland.

2. Plaintiff Sucampo Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 4520 East-West Highway, 3rd Floor, Bethesda, Maryland 20814.

3. Plaintiff R-Tech Ueno, Ltd. is a Japanese corporation having a principal place of business at NBF Hibiya Bldg., 10F, 1-1-7 Uchisaiwaicho, Chiyoda-ku, Tokyo 100-0011, Japan.

4. Plaintiff Takeda Pharmaceutical Company Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

5. Plaintiff Takeda Pharmaceuticals USA, Inc. is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited in the United States. Takeda Pharmaceuticals USA, Inc. is organized and existing under the laws of the State of Delaware, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

6. Plaintiff Takeda Pharmaceuticals America, Inc. is a wholly owned subsidiary of Takeda Pharmaceuticals USA, Inc. Takeda Pharmaceuticals America, Inc. is organized and existing under the laws of the State of Delaware, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

7. Upon information and belief, Defendant Anchen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of California, having its principal place of business at 9601 Jeronimo Road, Irvine, California 92618, and is a wholly-owned subsidiary of Defendant Par Pharmaceutical, Inc.

8. Upon information and belief, Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977, and is a wholly-owned subsidiary of Defendant Par Pharmaceutical Companies, Inc.

9. Upon information and belief, Defendant Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

10. Upon information and belief, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. share common employees, officers and directors, including without limitation Patrick G. LePore, officer of Par Pharmaceutical, Inc. and the Executive Chairman of Par Pharmaceutical Companies, Inc., Paul V. Campanelli, President of Par Pharmaceutical, Inc. and Chief Executive Officer and Director of Par Pharmaceutical Companies, Inc., Thomas J. Haughey, officer of Par Pharmaceutical, Inc. and President and Director of Par Pharmaceutical Companies, Inc.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Anchen Pharmaceuticals, Inc. by virtue of, *inter alia,* having availed itself of the rights and benefits of Delaware law and having engaged in systematic and continuous contacts with the State of Delaware.

13. This Court has personal jurisdiction over Par Pharmaceutical, Inc. because it is a corporation organized and existing under the laws of the State of Delaware and, by virtue of, *inter alia,* having availed itself of the rights and benefits of Delaware law and having engaged in systematic and continuous contacts with the State of Delaware.

14. This Court has personal jurisdiction over Par Pharmaceutical Companies, Inc. because it is a corporation organized and existing under the laws of the State of Delaware

and, by virtue of, *inter alia,* having availed itself of the rights and benefits of Delaware law and having engaged in systematic and continuous contacts with the State of Delaware.

15. Upon information and belief, Anchen Pharmaceuticals, Inc. is in the business of, among other activities, offering for sale, selling and/or importing copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

16. Upon information and belief, Par Pharmaceutical, Inc., alone and through its parent Par Pharmaceutical Companies, Inc., is in the business of, among other activities, offering for sale, selling and/or importing copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

17. Upon information and belief, Par Pharmaceutical Companies, Inc. markets and sells generic drugs throughout the United States, including in the State of Delaware, and therefore Par Pharmaceutical Companies, Inc. has engaged in systematic and continuous business within this judicial district.

18. Upon information and belief, Par Pharmaceutical, Inc. makes regulatory submissions to the United States Food and Drug Administration ("FDA"), including submissions on behalf of Par Pharmaceutical Companies, Inc.

19. Upon information and belief, the acts of Par Pharmaceutical, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, assistance of, and at least in part for the benefit of, Par Pharmaceutical Companies, Inc.

20. Upon information and belief, Anchen Pharmaceuticals, Inc. and Par Pharmaceutical, Inc. collaborated in the research, development, submission of, and continuous correspondence with the FDA regarding Anchen Pharmaceuticals, Inc.'s Abbreviated New Drug

Application No. 201442 ("ANDA") for lubiprostone oral capsules, 8 mcg and 24 mcg ("the ANDA Products") and intend to collaborate in the commercial manufacture, marketing, offer for sale and sale of the ANDA Products throughout the United States, including in the State of Delaware, in the event the FDA approves the ANDA.

21. Upon information and belief, Anchen Pharmaceuticals, Inc. sent a first letter to Plaintiffs dated December 26, 2012 ("First Notice Letter"), which was on a letterhead bearing Par Pharmaceutical, Inc.'s logo. The First Notice Letter was signed by Michelle Bonomi-Huvala, with the title of Senior Vice President, Corporate Regulatory Affairs, Par Pharmaceutical, Inc. Upon information and belief, Anchen Pharmaceuticals, Inc. sent a second letter to Plaintiffs dated January 24, 2013 ("Second Notice Letter"), which was on a letterhead bearing Par Pharmaceutical, Inc.'s logo. The Second Notice Letter was also signed by Michelle Bonomi-Huvala with the title of Senior Vice President, Corporate Regulatory Affairs, Par Pharmaceutical, Inc.

22. Upon information and belief, Par Pharmaceuticals, Inc. at least through its Corporate Regulatory Affairs Department, has contributed to ANDA No. 201442.

23. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

FACTUAL BACKGROUND

24. Plaintiff Sucampo Pharmaceuticals, Inc. holds approved New Drug Application ("NDA") No. 021908 for which the FDA granted approval on January 31, 2006 for 24 mcg lubiprostone capsules and on April 29, 2008 for 8 mcg lubiprostone capsules. The lubiprostone capsules described in NDA are currently indicated chronic idiopathic constipation in adults and for the treatment of irritable bowel syndrome with constipation in women at least 18 years old; they are marketed in the United States under the trade name Amitiza®.

25. Sucampo AG owns United States Patent No. 6,414,016 ("the '016 patent") titled "Anti-Constipation Composition." The '016 patent was duly and legally issued on July 2, 2002. Sucampo AG owns United States Patent No. 7,795,312 ("the '312 patent") titled "Method for Treating Abdominal Discomfort." The '312 patent was duly and legally issued on September 14, 2010. Sucampo AG owns United States Patent No. 8,071,613 ("the '613 patent") titled "Anti-Constipation Composition." The '613 patent was duly and legally issued on December 6, 2011. Sucampo AG owns United States Patent No. 8,097,653 ("the '653 patent") titled "Dosage Unit Comprising a Prostaglandin Analog for Treating Constipation." The '653 patent was duly and legally issued on January 17, 2012.

26. The '016, '312, '613 and '653 patents are assigned to Sucampo AG. Takeda Pharmaceutical Company Limited is an exclusive licensee to the '016, '312, '613 and '653 patents. Takeda Pharmaceuticals USA, Inc. is a sublicensee of Takeda Pharmaceutical Company Limited. Takeda Pharmaceuticals America, Inc. is a sublicensee of Takeda Pharmaceuticals USA, Inc. Copies of the '016, '312, '613 and '653 patent are attached as Exhibits A-D respectively.

27. Sucampo AG and R-Tech Ueno, Ltd. co-own United States Patent No. 8,026,393 ("the '393 patent") titled "Soft-Gelatin Capsule Formulation." The '393 patent was duly and legally issued on September 27, 2011. Sucampo AG and R-Tech Ueno, Ltd. co-own United States Patent No. 8,338,639 ("the '639 patent") titled "Soft-Gelatin Capsule Formulation." The '639 patent was duly and legally issued on December 25, 2012.

28. The '393 and '639 patents are assigned to R-Tech Ueno, Ltd. and Sucampo AG. Takeda Pharmaceutical Company Limited is an exclusive licensee to the '393 and '639 patents. Takeda Pharmaceuticals USA, Inc. is a sublicensee of Takeda Pharmaceutical

Company Limited. Takeda Pharmaceuticals America, Inc. is a sublicensee of Takeda Pharmaceuticals USA, Inc. Copies of the '393 and '639 patent are attached as Exhibits E and F respectively.

29. The '016, '312, '613, '653, '393 and '639 patents are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Amitiza®.

30. Upon information and belief, Anchen Pharmaceuticals, Inc., in collaboration with, or with the assistance from, Par Pharmaceuticals, Inc., submitted to the FDA ANDA No. 201442, including a certification with respect to the '016, '312, '393, '613, '653 and '639 patents under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Products prior to expiration of the '016, '312, '613, '653, '393 and '639 patents.

31. On December 26, 2012, Par Pharmaceutical, Inc. sent the First Notice Letter to Sucampo Pharmaceuticals, Inc., Sucampo AG and R-Tech Ueno Ltd., signed by Michelle Bonomi-Huvala, Senior Vice President Corporate Regulatory Affairs, Par Pharmaceutical, Inc., in which Par Pharmaceutical, Inc. represented that Anchen Pharmaceuticals, Inc. had filed the ANDA for the ANDA Products, including a certification with respect to the '016, '312, '613, '653, '393 and '639 patents, and that it sought approval of the ANDA prior to the expiration of those patents. Sucampo Pharmaceuticals, Inc. and Sucampo AG each received the First Notice Letter on January 2, 2013.

32. On January 24, 2013, Par Pharmaceutical, Inc. sent the Second Notice Letter to Sucampo Pharmaceuticals, Inc., Sucampo AG and R-Tech Ueno Ltd., signed by Michelle Bonomi-Huvala, Senior Vice President Corporate Regulatory Affairs, Par

Pharmaceutical, Inc., in which Par Pharmaceutical, Inc. represented that Anchen Pharmaceuticals, Inc. had filed the ANDA for the ANDA Products, including a certification with respect to the '639 patent, and that it sought approval of the ANDA prior to the expiration of the patent. Sucampo Pharmaceuticals, Inc. and Sucampo AG each received the Second Notice Letter on January 25, 2013.

33. Plaintiffs commenced this action within 45 days of the date of delivery of the First and Second Notice Letters.

FIRST COUNT FOR PATENT INFRINGEMENT

34. Plaintiffs repeat and re-allege paragraphs 1-33 as if fully set forth herein.

35. By seeking approval of its ANDA No. 201442 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products prior to the expiration of the '016, '312, '613, '653, '393 and '639 patents, Defendants have infringed those patents pursuant to 35 U.S.C. § 271(e)(2)(A).

36. The manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the ANDA Products by the Defendants prior to the expiration of the '016, '312, '613, '653, '393 and '639 patents, if approved by the FDA, would infringe one or more claims of those patents under 35 U.S.C. § 271.

37. By collaborating in the research, development, and submission of ANDA No. 201442 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products prior to the expiration of the '016, '312, '613, '653, '393 and '639 patents, Par Pharmaceuticals, Inc. has infringed those patents pursuant to 35 U.S.C. § 271(e)(2)(A).

38. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the ANDA No. 201442 be a date that is not earlier than the expiration date of the '016, '312, '613, '653, '393 and '639 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled.

39. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT

40. Plaintiffs repeat and re-allege paragraphs 1-39 as if fully set forth herein.

41. Upon information and belief, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 201442 to the FDA. On information and belief, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. were aware of the '016, '312, '613, '653, '393 and '639 patents when they engaged in these knowing and purposeful activities referred to above.

42. Under 35 U.S.C. §§ 271(b) and 271(e)(2)(A), Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. have induced infringement of '016, '312, '613, '653, '393 and '639 patents by actively and knowingly aiding and abetting the submission to the FDA of ANDA No. 201442. The filing of the ANDA by Anchen Pharmaceuticals, Inc. constitutes a direct act of infringement under 35 U.S.C. §271(e)(2)(A). Par Pharmaceutical, Inc.'s and Par Pharmaceutical Companies, Inc.'s active and knowing aiding and abetting Anchen Pharmaceuticals, Inc. in the filing of ANDA No. 201442 constitutes induced infringement.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

a. An order adjudging and decreeing that Defendants have infringed the '016, '312, '613, '653, '393 and '639 patents by submitting ANDA No. 201442 to the FDA;

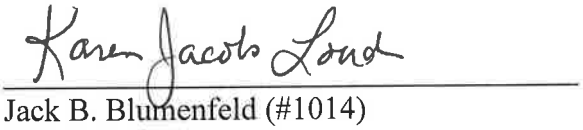
b. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) restraining and enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with them, from infringing the '016, '312, '613, '653, '393 and '639 patents by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product claimed in the aforementioned patents;

c. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of the ANDA No. 201442 be a date that is not earlier than the expiration date of the '016, '312, '613, '653, '393 and '639 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled;

d. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offers for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the '016, '312, '613, '653, '393 and '639 patents, within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

e. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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